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10/784,401

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Peter M. Bonutti

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SUITE 115

MIAMI, FL 33180

EXAMINER

TYSON, MELANIE RUANO

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,401	Applicant(s) BONUTTI, PETER M.	
	Examiner MELANIE TYSON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 16-19, 24 and 26-57 is/are pending in the application.
- 4a) Of the above claim(s) 16, 18, 26-31, 45 and 51-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 17, 19, 24, 32-44, 46-50 and 54-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 June 2009 has been entered. Claims 8-15, 20-23, and 25 remain cancelled. New claims 51-57 have been added. Claims 16 and 18 remain withdrawn from consideration. Upon further consideration, claim 17 reads on elected species III. Therefore, claim 17 is no longer withdrawn from consideration and has been examined. Furthermore, claims 26-31, 45, and new claims 51-53 read on non-elected species II (Figures 4-8), and thus have been withdrawn from consideration.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 17, 19, 24, 32-44, 46-50, and 54-57 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the biasing member as recited in claim 43 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 43 is objected to because of the following informalities: claim 43 contains a typographical error. Insert the term --to-- between the terms "surface" and "spread" in line 6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 24, 32-44, 46-50, and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A single claim which claims both an apparatus and the method steps of using the apparatus ("generating a magnetic field" recited specifically in claims 1 and 40; "the magnetic field generator is positioned external to tissue" recited specifically in claims 6 and 24) is indefinite under 35 U.S.C. 112, second paragraph. Appropriate correction is required. The remaining claims are rejected as depending from claims 1 or 40, or reciting the same limitations described above.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 24, 32-44, 46-50, and 57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are rejected under 35 U.S.C. 101 based on the theory that the claims are directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101, which is drafted so as to set forth the statutory classes of invention in the alternative only. See MPEP 2173.05(p).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 17, 19, 24, 32, 35-37, 40, 41, 44, 46, and 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al. (U.S. Patent No. 5,824,009).

Fukuda discloses a device (see entire document) comprising a first tissue engaging surface (1) being configured to releasably hold a medical implement (needle, wherein the needle body 3a may be formed of a magnet which constitutes a magnetic field generator and 3a is disposed in the first tissue engaging surface) that is temporarily affixed to the magnetizable material when released from the first tissue engaging surface, having a suture (3b) attached thereto, and to contact a first tissue section, a second tissue engaging surface (2) being movable relative to the first engaging surface (the surfaces are both movable relative to each other) in order to contact a second tissue and to penetrate the medical implement into the tissue, a pivot connecting the first and second tissue engaging surfaces (for example, see Figure 1), a magnetizable material being disposed in the second tissue engaging surface (portion 5; for example, see column 6, lines 10-12), a biasing member (first and second handles 7, 7) to spread (open) and to mechanically urge or compress the tissue engaging surfaces, and a holder (4), wherein the magnetic field generator and magnetizable material do not dissolve or absorb within the body and thus are considered “permanent” as recited in

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the claims, and the tissue engaging surface with magnetic field generator may be positioned anywhere along or surrounding the tissue and thus the generator is considered to be “selectably” positionable and the magnetic field is considered “alterable.” With further respect to claims 1 and 40, Fukuda's device is structured as recited in the claims and thus the magnetic field generated by Fukuda's generator is capable of driving the medical implement by magnetic attraction alone at a moment, for example, when the surfaces are engaging tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-7, 33, 34, 38, 39, 42, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al., as applied to claims 1 and 40 above, in view of Goradia (U.S. Patent No. 6,179,850 B1). Fukuda discloses the claimed invention except for an electromagnetic field generator, a variable magnetic field

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strength, and a magnetic field generator that is activatable to reverse a polarity to enable spreading [repelling] or compression of the tissue engaging surfaces and deactivatable to enable the user to move the tissue engaging surfaces, including the implement, back and forth through tissue, wherein the magnetizable material includes iron or an electromagnet.

Goradia discloses an apparatus comprising first and second and tissue engaging surfaces that utilizes a magnetic material and a magnetic field generator for creating a magnetic field that causes compression of the tissue engaging surfaces (see entire document). Goradia teaches the magnetic field generator may comprise an electromagnet having a variable magnetic field strength in that the magnetic field of an electromagnet can be manipulated by controlling the amount of electric current applied, wherein the electromagnet is activatable to reverse a polarity to enable spreading [repelling] or compression of the tissue engaging surfaces and deactivatable to enable the user to move the tissue engaging surfaces back and forth through tissue, (for example, see column 10, lines 24-34). The substitution of one known element (an electromagnet as shown in Goradia) for another (a permanent magnet as shown in Fukuda) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of magnetic material would have yielded predictable results, namely, a system that would enable a user to manipulate the magnetic field, thus providing a versatile device that can produce sufficient strength to clamp opposing tissue in different applications, and facilitate re-opening and resetting of the tissue engaging surfaces.

With further respect to claims 38 and 39, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the magnetizable material of iron or an electromagnet, since it has been held to be within the general skill of a worker in the art to select a known material (in which Goradia discloses iron material and electromagnetic material are well known) on the basis of its suitability for the intended use as a matter of design choice.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al., as applied to claim 40 above, in view of Wilkinson (U.S. Patent No. 3,577,991). Fukuda discloses the claimed invention except for a separate biasing member for spreading the tissue engaging surfaces. Wilkinson discloses an apparatus for moving an implement comprising tissue engaging surfaces (13 and 14) and handles (10 and 11) for compressing the tissue engaging surfaces. Wilkinson teaches a biasing member (15) for holding the tissue engaging surfaces in an open configuration (for example, see column 2, lines 1-4). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Wilkinson to the device of Fukuda would have yielded predictable results and resulted in an improved system, namely, a system that would automatically bias the tissue engaging surfaces open, thus enabling a user to operate the tissue engaging surfaces with only a single input to the handles (i.e., compressing the handles together closes the tissue engaging surfaces and releasing the handles automatically spreads the tissue engaging surfaces open).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 17, 19, 24, 32-39, 44, 46-50, 54, and 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-7, 17, 19, 24, 32-37, 39, 44, 46-50, 54, and 55 of the examined application are generic to the device recited in claims 11-26 of the '765 patent. That is, claims 11-26 of the '765 patent fall entirely within the scope of claims 1-7, 17, 19, 24, 32-37, 39, 44, 46-50, 54, and 55 of the examined application, or, in other words, claims 1-7, 17, 19, 24, 32-37, 39, 44, 46-50, 54, and 55 of the examined application are anticipated by claims 11-26 of the '765 patent. Specifically, since a suture passer is a

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species of the generic category defined by “an apparatus for moving a medical implement,” the device of claims 1-7, 17, 19, 24, 32-37, 39, 44, 46-50, 54, and 55 are anticipated by claims 11-26 of the '765 patent reciting “a suture passer.”

Claim 38 would have been obvious over the '765 patent claims. Specifically, the '765 patent discloses the claimed invention contemplates forming the magnetizable material of iron. Therefore, claim 38 is considered an obvious variation of the invention recited in the '765 patent claims.

Claims 40-43, 56, and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2 in view of U.S. Patent No. 3,577,991 (Wilkinson).

Here, claims 11-26 of U.S. Patent No. 6,719,765 B2 recites a device for inserting a suture through tissue comprising electromagnets. The device of claims 11-26 differ from claims 40-43, 56, and 57 herein in that it fails to disclose the presence of a pivot connecting the handles and a biasing member for spreading the tissue engaging surfaces. However, Wilkinson discloses an apparatus for moving an implement comprising tissue engaging surfaces (13 and 14) and handles (10 and 11) for compressing the tissue engaging surfaces. Wilkinson teaches a pivot (12) connecting the handles in order to operate the tissue engaging surfaces and a biasing member (15) for holding the tissue engaging surfaces in an open configuration (for example, see column 2, lines 1-4). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Wilkinson to the device of the '765 patent claims would have yielded predictable results and resulted in an improved

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system, namely, an operable system that would automatically bias the tissue engaging surfaces open, thus enabling a user to operate the tissue engaging surfaces with only a single input to the handles (i.e., compressing the handles together closes the tissue engaging surfaces and releasing the handles automatically spreads the tissue engaging surfaces open).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Melanie Tyson/
Examiner, Art Unit 3773
August 3, 2009